



## ATTACHMENT B

### REMARKS

By this amendment, in conjunction with the RCE filed herewith, Applicants have now amended Claim 1 in the manner suggested by the Examiner and in addition have added Claims 31 and 32 which are dependent claims and which include other patentable features of the present application. As a result of these amendments, Claims 1, 3-9, 11, 16, and 18-32 are now pending, although claims 5-8, 16, 18-22 and 24-30 have been considered withdrawn. In addition, Claim 14 has been canceled without prejudice. Applicants respectfully submit that the present application is in condition for allowance for the reasons as set forth below.

In the Official Action, Claim 1 and its dependent claims were rejected under 35 U.S.C. §112, second paragraph, and this objection has been overcome in that Applicants have adopted the equivalent language suggested by the Examiner which overcomes the rejection. In addition, Claims 3 and 14 were objected to as having overlapping scope, and this objection is overcome in that Claim 14 is now canceled without prejudice. Applicants submit that the claims as amended are entirely proper under 35 U.S.C. § 112.

In the Official Action, the Examiner maintained rejections of Claims 1, 3, 4, 14 and 23 under the judicially created doctrine of obviousness-type double patenting over claims 28, 29, 40-42, 45, 46, 48 of the co-pending Application No. 09/978,343. In addition, the Examiner maintained rejections of Claims 1, 3, 4, 13 and 14 under 35 U.S.C. § 102(b) as being anticipated by Hostetter et al U.S. Patent No. 5,886,151 (hereinafter "the '151 patent"). Claims 1, 9 and 11 were rejected under 35 U.S.C. §

103(a) as being unpatentable over the '151 patent. Even though the Examiner could not point to any specific disclosure in the prior Hostetter patents and patent applications which referred at all to antibodies capable of binding to the propeptide region, the Examiner maintained the rejection on the grounds that the prior patents disclosed isolated antibodies to Int1p and that the prior antibodies "block the adhesion of *Candida albicans* to epithelial cells." See Official Action at page 5. For reasons as set forth below and in the attached Declaration of Dr. Margaret Hostetter, M.D., the Examiner's rejections, insofar as applied to the claims as amended, are respectfully traversed.

With regard to both the double patenting rejection and the rejections under 35 U.S.C. §102 and 103, the Examiner alleges that the prior Hostetter patents and patent applications disclosed various antibodies to the Int1p protein, and that these antibodies were shown to block the adhesion of *Candida* to epithelial cells and would have inherently also had the functional ability to prevent cleavage of the propeptide and subsequent inhibition of T lymphocyte activity. Such comments not only reflect a misunderstanding of the present invention, they are not correct in that the prior Hostetter applications and patents did **not** disclose or suggest antibodies which could prevent cleavage of the superantigen and inhibition of T lymphocyte activation. As indicated in the attached Declaration of the first-named inventor of the present application. Dr. Margaret K. Hostetter, M.D., the fact that the prior antibodies disclosed and claimed in their previous patents and application were able to block adhesion of *Candida* to epithelial cells is totally irrelevant to the unrelated ability of specific antibodies not previously known or observed to prevent the cleavage of the propeptide and thus inhibit T lymphocyte activation.

Indeed, as reflected in the attached Declaration, the present invention represents a novel type of antibody that was not observed or disclosed with regard to the earlier patent references of Dr. Hostetter's inventive group, namely one that could inhibit T lymphocyte activation by specifically binding to the propeptide and preventing its cleavage wherein it would become a superantigen. As a result, none of the prior disclosures, inherently or otherwise, showed the ability of any antibody disclosed therein to achieve T lymphocyte activation, and as shown in the attached declaration, the fact that prior antibodies were successful in blocking yeast adhesion is totally different and unrelated to an ability to specifically block cleavage of the propeptide and achieve subsequent inhibition of T lymphocyte activation which was not heretofore possible.

Even further, as set forth in the attached Declaration<sup>1</sup>, it is indeed the case that the specific antibodies of the present application were tested with regard to their ability to inhibit T lymphocyte activation, and the results with antibodies in accordance with the present invention unexpectedly showed a remarkably high percentage of inhibition of T lymphocyte activation. Accordingly, the present invention provides unexpected benefits over the prior work wherein there was no disclosure or suggestion of antibodies that could prevent cleavage of the propeptide and thus be useful in inhibiting T lymphocyte activation.

In short, it is clearly the case that the prior Hostetter applications and patents did not disclose or suggest, either inherently or directly, an antibody which was capable of binding the propeptide of the Int1p protein, and accordingly did not disclose or suggest antibodies in accordance with the present invention which have been shown to inhibit

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<sup>1</sup> An executed copy of this Declaration will follow shortly.

the T lymphocyte activation associated with yeasts such as *Candida albicans* in a manner not previously possible using the prior Hostetter antibodies.

Accordingly, the claimed invention is clearly not anticipated or made obvious by the cited Hostetter references, either singly or in combination, and the Examiner's rejection on the basis of these references is respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present invention has now been placed in condition for immediate allowance, and such action is earnestly solicited.

#### **END OF REMARKS**

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